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TESTIMONY

# ADDRESSING ANTICOMPETITIVE CONDUCT IN PHARMACEUTICAL MARKETS: ANTITRUST ENFORCEMENT IS ROBUST AND EFFECTIVE, BUT ADDITIONAL MARKET-ORIENTED LEGAL REFORM WOULD BE HELPFUL

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US Senate Committee on the Judiciary, Subcommittee on Competition Policy, Antitrust, and Consumer Rights
A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets

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Chair Klobuchar, Ranking Member Lee, and distinguished members of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights:

My name is Alden Abbott, and I am a senior research fellow at the Mercatus Center at George Mason University. My research focuses primarily on antitrust and competition policy. I formerly served as general counsel of the Federal Trade Commission (FTC) and as a senior manager in the FTC's Bureau of Competition. I have also served in the Antitrust Division and Office of Legal Counsel at the US Department of Justice (DOJ). I welcome the opportunity to give testimony that highlights key considerations in addressing anticompetitive conduct and consolidation in prescription drug markets.

In this testimony, I will focus on three key points:

1. Federal antitrust enforcement has been robust and effective in promoting prescription drug market competition. New antitrust enforcement tools are not needed, but additional resources to support FTC and DOJ enforcement are warranted.
2. Antitrust enforcement directed at prescription drug markets should remain attentive to potential efficiencies associated with the practices under review, including the importance of protecting the legitimate exercise of intellectual property rights. Specialized legislation generally is not appropriate in this area.
3. Antitrust enforcement alone will not eliminate all competitive problems in prescription drug markets or in healthcare in general. Absent fundamental regulatory reform of the healthcare system, significant competitive distortions that hamper competition will remain.

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## FEDERAL ANTITRUST ENFORCEMENT HAS BEEN ROBUST AND EFFECTIVE IN PROMOTING PRESCRIPTION DRUG MARKET COMPETITION, BUT ADDITIONAL RESOURCES TO SUPPORT FTC AND DOJ ANTITRUST ENFORCEMENT ARE WARRANTED

The FTC and DOJ have many decades of experience studying and bringing appropriate antitrust enforcement actions concerning healthcare markets in general and the pharmaceutical sector in particular. Furthermore, the FTC has also carried out public hearings, undertaken sectoral investigations, and issued numerous reports on competition policy in these areas.

The broad scope of the FTC's current enforcement efforts in the pharmaceutical sector is described in some detail in an April 2021 FTC staff report produced by the FTC Bureau of Competition Health Care Division.[1] This report summarizes the many recent FTC initiatives in this area. These include enforcement actions directed at monopolization and agreements not to compete involving pharmaceutical products; mergers involving pharmaceutical products; mergers involving distribution; and agreements involving monopolization, price and price-related terms, and schemes to obstruct innovative methods of delivering and financing pharmaceutical products. In addition, this report describes a variety of FTC industry guidance statements and FTC "friend of the court" briefs (filed in private antitrust suits) dealing with pharmaceutical products and distribution issues (including such "hot topics" as reverse payments, product hopping, restricted distribution, the Noerr-Pennington Doctrine, regulatory issues, and market definition issues).

The DOJ's Antitrust Division has been particularly busy lately prosecuting hard-core cartel conduct by generic drug manufacturers. A March 2021 Antitrust Division update describes the impressive results of the division's ongoing investigation in this area:

> In recent years, the Division has uncovered price-fixing, bid-rigging, and customer-allocation schemes in one of the most important markets for the health and wallets of American consumers: the generic drug industry. Indeed, nearly 90% of all prescriptions in the United States are filled with generic drugs.
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> To date, the investigation has resulted in charges against seven generic pharmaceutical companies and four senior executives for conspiring to fix prices, rig bids, and allocate customers for essential generic drugs relied on by millions of American consumers, including the elderly and vulnerable, to treat a range of diseases and conditions. Of the four executives charged, three have pleaded guilty. Of the seven companies, five have admitted to the charged conduct and entered into deferred prosecution agreements (DPAs) to resolve the charges, under which they collectively agreed to pay over $426 million in criminal penalties for collusion that affected over $1 billion of generic drug sales. Most recently, in July 2020, Taro Pharmaceuticals U.S.A., Inc. was charged for participating in two conspiracies to fix prices, rig bids, and allocate customers that impacted over $500 million in sales of generic drugs used to prevent and control seizures and treat bipolar disorder, pain and arthritis, and various skin conditions. The company entered into a DPA to resolve the charges under which it agreed to pay a $205.7 million criminal penalty—the highest ever for a domestic cartel.[2]

These two recent examples of the government dealing with pharmaceutical competition tell a success story. Based on my prior government experience and my review of current developments, I conclude that the FTC and DOJ have done an outstanding job of enforcing the antitrust laws in the

1. Federal Trade Commission, *Overview of FTC Actions in Pharmaceutical Products and Distribution*, April 2021.
2. "Generic Investigation Targets Anticompetitive Schemes," US Department of Justice, updated March 24, 2021, https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes.

pharmaceutical sector.[3] Moreover, I believe that the existing antitrust laws provide federal enforcers ample legal tools to continue to carry out their enforcement mission in superlative fashion in this area.[4] As I indicated in recent testimony before the House Subcommittee on Antitrust, Commercial, and Administrative Law,[5] however, the FTC and DOJ would benefit from additional resources to carry out their antitrust enforcement duties. The need for more resources is particularly acute with regard to pharmaceutical enforcement, given the great economic significance and complexity of pharmaceutical market issues.

## ANTITRUST ENFORCEMENT DIRECTED AT PRESCRIPTION DRUG MARKETS SHOULD REMAIN ATTENTIVE TO POTENTIAL EFFICIENCIES AND TO PROTECTING THE LEGITIMATE EXERCISE OF INTELLECTUAL PROPERTY RIGHTS; SPECIALIZED LEGISLATION IS NOT APPROPRIATE IN THIS AREA

Apart from per se illegal cartel conduct, federal antitrust enforcers apply the antitrust rule of reason when assessing potentially anticompetitive pharmaceutical market practices. Doing so involves weighing whether particular conduct under scrutiny yields consumer-welfare-enhancing efficiencies that would offset its potential anticompetitive effects. These may include, among other possible socially desirable effects, efficiencies in pharmaceutical product distribution practices; efficiencies affecting the settlement of pharmaceutical litigation; and innovation-related efficiencies associated with patenting practices in pharmaceuticals. It is unwise to generalize about the presence or likelihood of such efficiencies in the abstract. Antitrust enforcement involves the assessment of detailed case-specific facts, including facts bearing on the verifiability and magnitude of possible efficiencies. Although efficiencies should not be assumed, neither should they be summarily discounted. Careful evaluation and weighing of all effects, procompetitive and anticompetitive, are required, if the rule of reason is to be applied in an optimal, cost-beneficial fashion.

In the pharmaceutical sector, issues of anticompetitive harm and procompetitive efficiencies often are associated with patents. Harm may arise from the strategic use of patents to delay or deter entry from potential competitors. At the same time, patents may facilitate the efficient and innovation-enhancing distribution of new technologies and may act as beacons to attract investments in R&D that help generate dynamic efficiencies through the creation of new products and services.[6] In assessing particular

3. For example, anticompetitive "reverse payment" litigation settlements (whereby a brand name pharmaceutical company pays a generic pharmaceutical producer to delay entering the market) appear to have been disincentivized owing to vigorous FTC enforcement. According to a December 2020 FTC staff report analyzing recent pharmaceutical patent settlement agreements, very few agreements involved reverse payments that are likely to be anticompetitive. Commenting on this report, then-FTC Chair Joseph Simons states that "the report shows, following the [Supreme Court's] Actavis decision [submitting reverse payments to antitrust scrutiny] and subsequent case law applying it, a continued decline in use of the types of reverse-payment agreements that are most likely to harm consumers." Federal Trade Commission, "FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors," press release, December 3, 2020, https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent.

4. More generally, as I stated in April 2021 testimony before the House Subcommittee on Antitrust, Commercial, and Administrative Law, "I do not believe that major statutory changes in the antitrust field would be helpful. . . . Although a few marginal adjustments to the antitrust statutes appear appropriate, such as elimination of the nonprofit exception to FTC jurisdiction, the mainstream consensus consumer-welfare approach should be retained. . . . In my opinion, the FTC staff possesses the legal tools (with the exception of the nonprofit limitation, discussed earlier) to fully investigate and take action against anticompetitive behavior in [the health care] sector." Alden F. Abbott, "Lack of Resources and Lack of Authority over Nonprofit Organizations Are the Biggest Hindrances to Antitrust Enforcement in Health Care" (Testimony before the US House Committee on the Judiciary, Subcommittee on Antitrust, Commercial, and Administrative Law, Mercatus Center at George Mason University, Arlington, VA, April 29, 2021), 3–4.

5. Abbott, "Lack of Resources and Lack of Authority," 1–2.

6. F. Scott Kieff, *Views of the Honorable F. Scott Kieff, Commissioner, United States International Trade Commission, on the United States Federal Trade Commission's and the United States Department of Justice Antitrust Division's Joint Guidelines for the Licensing of Intellectual Property* (Washington, DC: International Trade Commission, September 23, 2016.

pharmaceutical market practices, antitrust enforcers should seriously consider the possible efficiency-related ramifications, not just the potential competitive harm, arising out of the use of patents.

Congress should exercise restraint and precision when legislating with respect to particular institutional features of pharmaceutical markets (for example, the role of pharmaceutical benefit managers or other specialized entities).[7] Without compelling evidence that a particular feature has no potential redeeming efficiency benefits under any conditions, it is best, as a general matter, to rely on case-by-case antitrust enforcement evaluations of the role of such features in particular settings. That approach avoids the risk that a blanket legislative classification would eliminate many practices that frequently yield efficiencies and enhanced consumer welfare in the pharmaceutical sector.

## ANTITRUST ENFORCEMENT ALONE WILL NOT ELIMINATE ALL COMPETITIVE PROBLEMS IN PHARMACEUTICAL MARKETS; ABSENT SUBSTANTIAL REGULATORY REFORM, SIGNIFICANT DISTORTIONS OF COMPETITION WILL REMAIN

Although effective antitrust enforcement is of course important, it cannot be expected to eliminate all competitive problems in pharmaceutical markets. As FTC Commissioner Christine Wilson has stated, speaking more generally of the healthcare system,

> The health care system is so fundamentally broken that antitrust cannot fix all that ails it. I believe many of these problems come down to consumers' ability and incentive to choose among different products and services. Because insurers pick up much of the tab, one set of consumers—patients—have very little incentive to compare the prices of various health care providers. Even if they were inclined to comparison shop, it's not clear they could, given the opacity of most prices. And the ability to comparison shop based on quality—in other words, patient outcomes—is even more limited, given the dearth of data available to patients.[8]

Like the broader US healthcare system itself, pharmaceutical markets are rife with distortions related to current regulation. To take just one example, professor Joanna Shepherd has explained "that the current system of government price controls and distortive rebates creates perverse incentives for drugmakers to continue increasing drug list prices."[9]

Non-antitrust-related pharmaceutical market reform—and, more generally, healthcare reform overall—would be a most worthwhile endeavor. It should be acknowledged that the federal antitrust agencies have over the years done an outstanding job in calling for statutory and legislative reforms to improve healthcare competition under both Republican and Democratic administrations.[10] Enhancing competition in healthcare markets (including, of course, pharmaceutical markets), whether through enforcement or legislative and regulatory reform, has been and should remain a nonpartisan endeavor.

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7. Nevertheless, targeted statutory amendments, narrowly tailored to address specific competitive healthcare sector problems, may be appropriate in certain circumstances. A good example is the newly minted CREATES (Creating and Restoring Equal Access to Equivalent Samples) Act, which deals with regulatory abuses that had allowed branded pharmaceutical companies to forestall competition from both generic drug and biosimilar producers. The CREATES Act, which was enacted in December 2019, establishes a private right of action that allows developers of generic drug and biological products to sue brand companies that refuse to sell them product samples needed to support their applications for regulatory approval. "Access to Product Samples: The CREATES Act," US Food and Drug Administration, current as of March 13, 2020, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act.
8. Christine S. Wilson, "The FTC's Ongoing Efforts to Promote Competition and Choice in Our Health Care System" (remarks, The Price of Good Health – 2020 and Beyond, Council for Affordable Health Coverage, Washington, DC, January 16, 2020), 12.
9. Joanna Shepherd, "Drug Prices and Distortions in the Pharmaceutical Market," *Truth on the Market*, January 11, 2019.
10. Maureen Ohlhausen, "Beyond Law Enforcement: The FTC's Role in Promoting Health Care Competition and Innovation," *Health Affairs Blog*, January 26, 2015; "Healthcare Competition Advocacy," US Department of Justice, accessed April 26, 2021, https://www.justice.gov/atr/health-care-competition-advocacy.

## CONCLUSION

Federal antitrust enforcement has been robust and effective in promoting prescription drug market competition and thereby enhancing consumer welfare. New antitrust enforcement tools are not needed, nor is specialized pharmaceutical legislation, but additional resources to support FTC and DOJ enforcement are warranted. Antitrust enforcement in this area should fully take into account efficiencies, including innovation-related efficiencies associated with patents. Antitrust enforcement in itself, however, is not a panacea. Without significant regulatory reform, significant distortions of competition will remain in pharmaceutical markets.